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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/780,098

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David J. Allard

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EXAMINER

RANGREJ, SHEETAL

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/780,098	Applicant(s) ALLARD ET AL.	
	Examiner SHEETAL R. RANGREJ	Art Unit 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-18 and 20-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-18, and 20-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 30, 2009 has been entered.

Prosecution History Summary

2. Claims 5-15 and 19 are cancelled.
3. Claims 20-27 are new.
4. Claims 1-4, 16-18, and 20-27 are now pending.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, 16-18, and 24-27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

6. The basis of this rejection is based on recent Federal Circuit decisions and Supreme Court precedent in particular, *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876) which state that the process must:

(1) be tied to another statutory class (such as a particular apparatus); or

(2) transform underlying subject matter (such as an article or materials) to a different state or thing.

For a claimed invention to be statutory subject matter eligible, the claimed invention must fall within a judicial exception. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the recited claims should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps or positively recite subject matter that is being transformed for example by identifying the material that is being changed to a different state.

7. In the present case, claims 1-4, 16-18, and 24-27 recite an abstract idea only. The claims recite steps and means for a) defining processes, b) forming links between processes, traversing processes by meeting exit requirements. These steps and means do not apply, involve, use, or advance the technological arts since they can be performed in the mind of the user or by use of a

pencil and paper. These steps and means only constitute an idea of how to define, linking and traversing processes.

8. While Applicants' claim encompasses "a system for permitting controlled access to medical information of a patient," the claim is not limited to such an embodiment. Applicants' claimed method steps, as recited in the body of claims 1 and 24, are not limited to process steps using particular structure or apparatus. To the contrary, looking only to the method steps recited in the body of claims 1 and 24, they would reasonably be interpreted to encompass a human being performing these steps. The Applicants' claim 24's preamble includes only a nominal recitation of a "computer system." Nominal recitations of structure in an otherwise ineligible method fail to make the method a statutory process. *See Benson*, 409 U.S. at 71-72. *In re Langemyr*.

9. Explicitly claiming the medium or structure in the body of the claim that performs the underlying process steps would serve to better recite the technological arts within the present set of claims.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-4, 16-18, and 20-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 16-18, and 20-27 recites limitations in “means plus function” language. The scope of a “means” limitation is defined as the corresponding structure or material set forth in the written description and equivalents thereof. See MPEP § 2181 through § 2186. If there is no disclosure of structure, material or acts for performing the recited function in the specification, the claim limitation lacks specificity, and fails to satisfy the requirements of 35 U.S.C. 112, second paragraph.

Recent court cases have held that simply reciting “software” without providing some detail about the means to accomplish the function is not enough. *See Aristocrat Techs. Austl. Pty v. Int'l Game Tech.*, ___ F.3d ___, 2008 U.S. App. LEXIS 6472, at *10 [86 USPQ2d 1235] (Fed. Cir. Mar. 28, 2008) (“For a patentee to claim a means for performing a particular function and then to disclose only a general purpose computer as the structure designed to perform that function amounts to pure functional claiming. Because general purpose computers can be programmed to perform very different tasks in very different ways, simply disclosing a computer as the structure designated to perform a particular function does not limit the scope of the claim to ‘the corresponding structure, material, or acts’ that perform the function, as required by section 112 paragraph 6.”). The Court in *Aristocrat* did not require a listing of source code or a highly detailed description of the algorithm to be used to achieve the claimed functions in order to satisfy 35 U.S.C. §112 paragraph 6. It did require, however, the disclosure of at least the algorithm that transformed the general purpose microprocessor to a “special purpose computer

programmed to perform the disclosed algorithm.” *WMS Gaming*, 184 F.3d at 1349. Thus the patent must disclose, at least to the satisfaction of one of ordinary skill in the art, enough of an algorithm or description of structure corresponding to the claimed function to provide the necessary structure under 35 U.S.C. §112 paragraph 6.

In the instant case, the “means plus *function*” language recited in claims 1-4, 16-18, and 20-27, in limitations lacks sufficient disclosed structure under 112, sixth paragraph, and is therefore indefinite under 112, second paragraph.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-4 and 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over
Hacker (6,988,075; hereinafter Hacker) in view of Kenneth D Mandl, Peter Szolovits, Isaac S
Kohane, David Markwell, and Rhona MacDonald **Public standards and patients' control: how**
to keep electronic medical records accessible but private • Commentary: Open approaches
to electronic patient records • Commentary: A patient's viewpoint BMJ, Feb 2001; 322: 283
– 287 (herein after Mandl).

14. As per claim 1, Hacker discloses a method of permitting controlled access to medical information comprising:

(1) establishing a storage means for storing the medical information of the patient
(Hacker: col. 7, lines 21-27);

(2) establishing a means for accessing the medical information by the patient or any other authorized user **(Hacker: col. 7, lines 56-66).**

(3) assigning each user with a unique ID **(Hacker: col. 7, 43-50)** and pin **(Hacker: col. 7, 43-50; i.e. alphanumeric passphrases; col. 7, 60-66)** and tracking and notifying the patient of who accessed the medical information, what was accessed, and when was access taken place **(Hacker: col. 7, 66-col. 8, 3)**. Although Hacker does not explicitly teach who accessed the medical information, it is obvious that who accessed the medical information is a pertinent information and the prior art suggests providing the information of who accessed the medical information.

Hacker does not explicitly teach controlling an authorization and a scope of access to the medical information by the patient according to an assigned role of a user accessing the medical information, by modifying an access control list; and wherein the access control list lists each authorized user and the assigned role of each authorized user.

Mandl teaches:

(3) controlling an authorization and a scope of access to the medical information by the patient according to an assigned role of a user accessing the medical information, by modifying an access control list **(Mandl: p. 284, section Confidentiality).**

Wherein the access control list lists each authorized user and the assigned role of each authorized user (**Mandl: p. 284, section Confidentiality**).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings with the motivation of providing a user with managing their own health record and providing a user with a secure data repository of their own medical record (**Mandl**).

15. As per claim 2, Hacker discloses the method of claim 1, wherein the storage means is a central repository (**Hacker: col. 7, lines 21-27**).

16. As per claim 3, Hacker discloses the method of claim 1, wherein the means for accessing the medical information is controlled using a universally unique identifier (**Hacker: col. 7, lines 42-63**).

17. As per claim 4, Hacker discloses the method of claim 1, wherein said controlling step is overridden by a registered emergency provider (**Hacker: col. 7, lines 66-67**).

18. As per claims **20-23**, it is an article of manufacture claim which repeats the same limitations of claims **1-4**, the corresponding method claim, as a collection of executable instructions stored on machine readable media as opposed to a series of process steps. Since the teachings of **Hacker and Mandl** disclose the underlying process steps that constitute the method of claims **1-4**, it is respectfully submitted that they likewise disclose the executable instructions that perform the steps as well. As such, the limitations of claims **20-23**, are rejected for the same reasons given above for claims **1-4**.

19. As per claims **24-27**, they are system claims which repeat the same limitations of claims **1-4**, the corresponding method claims, as a collection of elements as opposed to a series of process steps. Since the teachings of **Hacker and Mandl** disclose the underlying process steps

that constitute the methods of claims **1-4**, it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the limitations of claims **24-27** are rejected for the same reasons given above for claims **1-4**.

20. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hacker (6,988,075; hereinafter Hacker) in view of Kenneth D Mandl, Peter Szolovits, Isaac S Kohane, David Markwell, and Rhona MacDonald and further in view of Felsher (2002/0010679; hereinafter Felsher).

21. As per claim 16, Hacker and Mandl disclose the method of claim 1, but do not teach wherein the patient is compensated for permitting some of the medical information to be available and used by a research institution.

Felsher teaches wherein the patient is compensated for permitting some of the medical information to be available and used by a research institution (**Felsher: para. 310**).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings with the motivation of providing a medical history that may be of critical importance to the future of healthcare (**Felsher: para. 7**) and the need for privacy and security of a patient's information (**Felsher: para. 17**).

22. As per claim 17, Hacker and Mandl disclose the method of claim 1, but do not teach wherein during a doctor visit the patient provides access to the medical information for a time period long enough to support the visit at which point the access times out.

Felsher teaches wherein during a doctor visit the patient provides access to the medical information for a time period long enough to support the visit at which point the access times out (**Felsher: para. 354**).

The motivation to combine the teachings is the same as claim 16.

23. As per claim 18, Hacker and Snowden disclose the method of claim 1, but do not teach wherein access to the patient's medical information expires when a physician logs into another room/appointment.

Felsher teaches wherein access to the patient's medical information expires when a physician logs into another room/appointment (**Felsher: para. 359; i.e. second communication session**).

The motivation to combine the teachings is the same as claim 16.

Response to Arguments

24. Applicant's arguments filed for claims 1-4 and 16-18 have been fully considered but they are not persuasive.

25. Applicant argues that Hacker does not teach or suggest assigning each user with a unique ID and pin. Examiner disagrees with the applicant and reiterates that Hacker discloses a system having a unique access identification means (i.e. unique ID) and also giving a pass phrase to access the system (i.e. pin). Hacker teaches providing the provider with appropriate means for input of the unique access identification for patient identification and access along with unique pass phrases (i.e. pin) to access the patient information (Hacker: col. 7, 60-66).

26. Applicant argues that Mandl does not suggest using an access control list as the mechanism for controlling access. In response to Applicant's argument, **Examiner disagrees**. Mandl discloses the patient having preferences about different parts of his/her medical history by providing authorization independently; furthermore teachings that patients grant different access

rights to different providers based on their role and on the particular individual (Mandl: p. 284; section Confidentiality). According to the Applicant's specification, an example of an access control list could be providing access to parties based upon their assigned role (para. 23).

Conclusion

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEETAL R. RANGREJ whose telephone number is (571) 270-1368. The examiner can normally be reached on M-F 8:30-5:30.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you

would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/S. R. R./
Examiner, Art Unit 3686
April 10, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686